REMARKS

Applicant's counsel thanks the Examiner for the careful consideration given the application. Applicants respectfully request reconsideration of the present Patent Application, particularly in view of the above Amendments and following remarks.

Amendments to the Claims

Claim 1 has been amended as follows:

(i) by adding that the negative mould is made <u>by using a slip casting forming technology on the basis of the model</u>; this finds clear support in Claim 1 as originally filed and at page 9, line 4 of the application as filed;

(ii) by adding a final step of checking the finished product in terms of dimensions and shape <u>directly on the prototype resin model</u> and <u>by using the negative mould</u>; this finds clear support from page 10, line 21, to page 11, line 2 (step 7) of the application as filed.

No new matter has been added to the claims by the above Amendments.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner's rejection of Claims 1, 3 and 5-10 under 35 U.S.C. § 103(a) as being unpatentable over D'Urso (US 5,741,215) in view of Taboas et al. (US 2003/0006534) in view of Cima et al. (US 5,490,962) is respectfully traversed in view of the following arguments.

As already discussed in our previous response, D'Urso relates to a method for stereolithographic construction of implantable surgical prosthesis and/or an anatomical pathology model, said method comprising the steps of:

inputting into a data storage means scanning data relating to internal and/or external surfaces of anatomical pathology;

computing the stored scanning data according to a predetermined algorithm to reconstruct a plurality of two dimensional cross-sectional images of the anatomical pathology;

computing said plurality of two dimensional cross-sectional images according to a predetermined algorithm to generate a three dimensional coordinate data set for the anatomical pathology;

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and generating a three dimensional representation of said anatomical pathology by stereolithographic modeling of a cross linkable liquid polymer using selected sequential two dimensional coordinate data sets computed in preselected planes from said three dimensional coordinate data set.

As represented in Figure and explained at col. 9, lines 3-38 of D'Urso, after establishing a three dimensional coordinate data set for a region surrounding the defect, highly accurate boundary definitions are obtainable for the edge of the effect aperture as well as the cross sectional contours of region. A model for the defect is then created by using a three-dimensional stereolithographic technique. Once a satisfactory fit of model in the defect has been achieved, a cranioplastic implant may then be manufactured from the model, in acrylic or hydroxyapatite or other suitable material.

Therefore, the teaching derivable from D'Urso differs from the method according to Claim 1 as instantly submitted at least for the following features:
(i) D'Urso does not show the step of forming a negative mould starting from a (positive) model of the patient's bone defect, which is a negative of the patient's bone defect, which is then used to produce the sintered ceramic device; conversely, D'Urso teaches producing a ceramic device directly from the model of the defect obtained by a three-dimensional stereolithographic technique;
(ii) D'Urso does not teach producing a sintered ceramic semi-finished product whose dimensions and shape are slightly larger than those of the bone defect, and then subjecting the semi-finished product to mechanical processing and manual finishing to obtain the finished ceramic product having precise dimensions and shape of the bone defect; conversely, D'Urso teaches precisely fitting the model to the defect, and only subsequently producing the prosthetic ceramic device on the basis of the precise model;
(iii) D'Urso does not teach producing a sintered ceramic semi-finished product having a controlled and interconnected porosity of from 30% to 90%, said porosity having a bimodal distribution of the pore dimensions in a first range of from 0.1 to 125 microns and in a second range of from 125 to 2500 microns, as instantly claimed;
(iv) D'Urso does not teach finally checking the finished product in terms of dimensions and shape directly on the prototype resin model and by using the negative mould: according to D'Urso the model should be fitted precisely to the defect, and then on the basis of the model the final prosthetic ceramic device having the exact shape and dimensions is produced.

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The above differences (i), (ii) and (iv) cannot be derived by the other references cited by the Examiner.

As already discussed in our previous response, Taboas et al. do not teach producing <u>a negative mould of the patient's bone defect starting from a (positive) model of the bone defect to be reconstructed</u>, which in turn is obtained from a prototype resin model of the interested region by means of a three-dimensional stereolithograpic technique.

Conversely, according to Taboas et al., a mould for casting the designed scaffold is fabricated using direct deposition of the mould material by using 3D printing or other SFF (Solid Free Form) technologies (see paragraph [0058] of Taboas et al.) These technologies are based on a computer aided design technique and/or an image based design technique (see paragraph [0015]) which generates a computational design of the scaffold shape and dimensions. Therefore, differently from the present invention, Taboas et al. start from <u>a computer generated model of the scaffold to be produced</u>, on the basis of which the final, real scaffold is achieved.

Conversely, according to the present invention, a three-dimensional electronic model is obtained by CAT technique of the part of the bone and of the bone defect to be reconstructed. On the basis of said model, a prototype resin model of the bone including the defect is obtained, from which a positive model of the scaffold is produced, which serves as a basis for a negative mould in which the scaffold is manufactured. Moreover, as set forth in Claim 1 as submitted herewith, the negative mould is produced from the positive model of the patient's bone defect <u>by using a slip casting forming technology</u>. It is apparent that this feature is not even suggested by Taboas et al., simply because Taboas et al. do not produce a positive model of the scaffold, therefore a slip casting forming technology cannot be implemented.

The process according to the invention is therefore much more complex than that suggested by Taboas et al., which simply requires the production of the scaffold mould on the basis of a computer generated design of the scaffold itself. The process, although highly automated, cannot guarantee the desired precision in the final scaffold.

Finally, Taboas et al. do not even suggest finally checking the finished product in terms of dimensions and shape directly on the prototype resin model and by using the negative mould, simply because the prototype resin model is not available to Taboas et al.

Therefore, it is apparent that one skilled in the art would not have even considered to combine D'Urso with Taboas, et al, since they start from different approaches: according to D'Urso a three dimensional model of the anatomical pathology (obtained by a stereolithographic technique) is necessary to produce the final prosthetic device (scaffold), while according to Taboas et al. the 3D computer generated model of the prosthetic device can be directly used to obtain a mould for the final scaffold.

In the outstanding Office action, the Examiner also cites a new reference, Cima, et al. (US 5,490,962). Cima et al. relates to solid free-form techniques for making medical devices for controlled release of bioactive agent and implementation using computer aided design. It is apparent that the newly cited reference is not relevant to the present invention, since Cima, et al. do not give any hint on how to manufacture a prosthetic implant which should fit to fill a patient's bone defect. This secondary reference is cited by the Examiner only to show that the bimodal distribution of pores in the final scaffold as set forth in Claim 1 of the present application is already known in the art. From the above discussion, it is apparent that the above bimodal distribution is a secondary feature of the present invention, the latter mainly differing from the cited references for other reasons, which directly refer to the process for producing and not to the obtained product.

Additionally, the Examiner rejects Claim 2 under 35 U.S.C. § 103(a) as being unpatentable over D'Urso in view of Taboas et al. in view of Cima et al., as applied to Claim 1, and further in view of Cummings, et al. (US 2004/0152034). This rejection is clearly moot in view of the above arguments relating to the combination of D'Urso and Taboas et al. and Cima et al. Reference is made to the arguments already expounded in our previous response.

Taking into account the above arguments, the non-obviousness of the claimed invention is apparent. It is clear from the foregoing that the claims as now presented define over the prior art.

A Notice of Allowance is accordingly now in order and is respectfully requested. If any further fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. BUG5-41416.

Respectfully submitted,

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